IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

In re Sitagliptin Phosphate ('708 & '921) Patent Litigation	C.A. No. 19-md-2902-RGA
MERCK SHARP & DOHME CORP., *Plaintiff*, v. AUROBINDO PHARMA LIMITED and AUROBINDO PHARMA USA, INC., *Defendants*.	C.A. No. 20-1099-RGA

AUROBINDO'S ANSWER, ADDITIONAL DEFENSES, AND COUNTERCLAIMS TO FIRST AMENDED COMPLAINT

Defendants Aurobindo Pharma Limited and Aurobindo Pharma USA, Inc. (collectively, "Defendants" or "Aurobindo"), by their attorneys, hereby respond and object to Plaintiff Merck Sharp & Dohme Corp. ("Merck") and its First Amended Complaint, dated February 17, 2021 involving the drug JANUMET® (sitagliptin phosphate; metformin hydrochloride), as follows:

1. **This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, and for a declaratory judgment of patent infringement under 28 U.S.C. §§ 2201 and 2202 and the patent laws of the United States, Title 35, United States Code, that arises out of Defendants' submission of Abbreviated New Drug Application ("ANDA") No. 214859 to the U.S. Food and Drug Administration ("FDA") seeking approval to commercially manufacture, use, offer for sale, sell, and/or import versions of JANUMET®**

(metformin hydrochloride; sitagliptin phosphate) prior to the expiration of U.S. Patent No. 7,326,708 ("the '708 patent") and U.S. Patent No. 8,414,921 ("the '921 patent").

ANSWER: Aurobindo admits that Plaintiff has brought an action for patent infringement under the Patent Laws of the United States, 35 U.S.C. §100 et seq., and a declaratory judgment under 28 U.S.C. §§ 2201 and 2202 and that Plaintiff has asserted that it arises from Aurobindo's Abbreviated New Drug Application ("ANDA") with the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture and sell a generic version of JANUMET® (sitagliptin phosphate; metformin hydrochloride) ("Janumet") ("Aurobindo's Generic Sitagliptin Phosphate Metformin Product"), but denies any remaining allegations of Paragraph 1.

2. **Aurobindo Pharma USA, Inc. ("Aurobindo Inc.") notified Merck by letter dated July 10, 2020 ("Aurobindo's Notice Letter") that it had submitted to the FDA ANDA No. 214859 ("Aurobindo's ANDA"), seeking approval from the FDA to engage in the commercial manufacture, use, offering for sale, sale, and/or importation of generic sitagliptin phosphate; metformin hydrochloride oral tablets ("Aurobindo's ANDA Product") prior to the expiration of the '708 patent and the '921 patent.**

ANSWER: Admitted that Aurobindo notified Merck that Aurobindo submitted to the FDA ANDA No. 214859.

3. **On information and belief, Aurobindo's ANDA Product is a generic version of Merck's JANUMET® product.**

ANSWER: Aurobindo admits that Aurobindo's ANDA Product is a generic version of the proprietary brand Janmuet, containing the same active ingredient.

PARTIES

4. **Plaintiff Merck is a corporation organized and existing under the laws of New Jersey, having its corporate offices and principal place of business at One Merck Drive, Whitehouse Station, New Jersey 08889.**

ANSWER: Aurobindo admits upon information and belief that Plaintiff Merck is a corporation organized and existing under the laws of New Jersey, and that it has a place of business at One Merck Drive, Whitehouse Station, New Jersey 08889. Except as so admitted, Aurobindo lacks information and knowledge sufficient to form a belief about the truth of the remaining allegations in paragraph 4 of the First Amended Complaint and therefore denies them.

5. **Merck is the holder of New Drug Application ("NDA") No. 22044 for JANUMET® (metformin hydrochloride; sitagliptin phosphate), which has been approved by the FDA.**

ANSWER: Admitted.

6. **On information and belief, Defendant Aurobindo Pharma, Ltd. is a corporation organized and existing under the laws of India having its corporate offices and principal place of business at Maitri Vihar, Plot #2, Ameerpet, Hyderabad 500038, Telangana, India. On information and belief, Aurobindo Pharma, Ltd. is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical drugs through various operating subsidiaries, including Aurobindo Pharma USA, Inc.**

ANSWER: Paragraph 6 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Aurobindo admits Aurobindo Pharma Ltd. is a corporation having a place of business at Maitri Vihar, Plot #2, Ameerpet, Hyderabad 500038, Telangana, India. Aurobindo also admits that Aurobindo Pharma Ltd. is in

the business of commercializing pharmaceutical products, including generic drug products and works with Aurobindo Pharma USA, Inc. in respect thereto.

7. **On information and belief, Defendant Aurobindo Pharma USA, Inc. is a corporation organized and existing under the laws of Delaware having its corporate offices and principal place of business at 279 Princeton-Hightstown Road, East Windsor, New Jersey 08520. On information and belief, Aurobindo Pharma USA, Inc. is in the business of, among other things, manufacturing and selling generic versions of pharmaceutical drug products throughout the United States, including Delaware.**

ANSWER: Paragraph 7 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Aurobindo admits Aurobindo USA is a corporation having a place of business at 279 Princeton-Hightstown Rd, East Windsor, NJ 08520-1401. Aurobindo also admits that Aurobindo USA is in the business of commercializing pharmaceutical products, including generic drug products. Aurobindo denies the remaining allegations of Paragraph 7.

8. **On information and belief, Aurobindo Pharma USA, Inc. is a wholly-owned subsidiary of Aurobindo Pharma, Ltd.**

ANSWER: Admitted.

9. **On information and belief, Aurobindo Pharma, Ltd. and Aurobindo Pharma USA, Inc. acted in concert to prepare and submit ANDA No. 214859 to the FDA.**

ANSWER: Paragraph 9 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Aurobindo admits that Aurobindo Pharma USA, Inc. and Aurobindo Pharma, Ltd. regularly work together to obtain regulatory approval of generic pharmaceutical products including ANDA No. 214859.

10. **On information and belief, Aurobindo Pharma, Ltd. and Aurobindo Pharma USA, Inc. know and intend that upon approval of Aurobindo's ANDA, Aurobindo Pharma, Ltd. and/or Aurobindo Pharma USA, Inc. will manufacture, market, sell, and distribute Aurobindo's ANDA Product throughout the United States, including in Delaware. On information and belief, Aurobindo Pharma, Ltd. and Aurobindo Pharma USA, Inc. are agents of each other and/or operate in concert as integrated parts of the same business group, including with respect to Aurobindo's ANDA Product, and enter into agreements that are nearer than arm's length. On information and belief, Aurobindo Pharma, Ltd. and Aurobindo Pharma USA, Inc. participated, assisted, and cooperated in carrying out the acts complained of herein. These two entities are hereafter collectively referred to as "Aurobindo."**

ANSWER: Paragraph 10 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Aurobindo admits that Aurobindo Pharma USA, Inc. and Aurobindo Pharma, Ltd. are in the business of, *inter alia*, the manufacture, marketing, sale, and distribution of generic pharmaceutical products, including the generic pharmaceutical product of ANDA No. 214859, and together participated, assisted, and cooperated in filing ANDA No. 214859, and that Aurobindo Pharma USA, Inc. is the United States-based wholly owned subsidiary of Aurobindo Pharma, Ltd. Aurobindo denies the remaining allegations of Paragraph 9 in respect of whether Aurobindo will or will not manufacture, market, sell, and distribute Aurobindo's ANDA Product throughout the United States, including in Delaware should it receive ANDA approval, as such is never certain given the vicissitudes of the marketplace (such as the number of entrants, and the date of Aurobindo's allowed entrance).

11. **On information and belief, following any FDA approval of ANDA No. 214859, Aurobindo Pharma, Ltd. and Aurobindo Pharma USA, Inc. will act in concert to distribute and sell Aurobindo's ANDA Product throughout the United States, including within Delaware.**

ANSWER: Due to the variability of market conditions over time, Aurobindo cannot respond one way or the other in regard to its ultimate intentions in regard to engaging in the marketing of Aurobindo ANDA Product in the United States, including in the State of Delaware, even upon receiving FDA approval to market. With respect to any remaining allegations of Paragraph 11, Aurobindo denies the same.

JURISDICTION

12. **This Court has jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.**

ANSWER: Paragraph 12 contains conclusions of law for which no response is required. To the extent that a response is required, Aurobindo admits for purposes of this case only that this Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331, 1338(a) and 2201-02. With respect to any remaining allegations of Paragraph 12, Aurobindo denies the same.

13. **This Court has personal jurisdiction over Aurobindo.**

ANSWER: Paragraph 13 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Aurobindo admits only that it will not contest personal jurisdiction for the purposes of this action. With respect to any remaining allegations of Paragraph 13, Aurobindo denies the same.

14. **Aurobindo Pharma, Ltd. is subject to personal jurisdiction in Delaware because, among other things, Aurobindo Pharma, Ltd., itself and through its wholly owned**

subsidiary Aurobindo Pharma USA, Inc., has purposefully availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here. On information and belief, Aurobindo Pharma, Ltd., itself and through its wholly owned subsidiary Aurobindo Pharma USA, Inc., develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including in the State of Delaware, and therefore transacts business within the State of Delaware, and/or has engaged in systematic and continuous business contacts within the State of Delaware. In addition, Aurobindo Pharma, Ltd. is subject to personal jurisdiction in Delaware because, on information and belief, it controls and dominates Aurobindo Pharma USA, Inc. and therefore the activities of Aurobindo Pharma USA, Inc. in this jurisdiction are attributed to Aurobindo Pharma, Ltd.

ANSWER: Paragraph 14 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Aurobindo admits that it is qualified to do business in Delaware, has appointed a registered person for service of process in Delaware, and sells some of its generic products in Delaware. Aurobindo admits that it will not contest personal jurisdiction for the purposes of this action. With respect to any remaining allegations of Paragraph 14, Aurobindo denies the same.

15. **Aurobindo Pharma USA, Inc. is subject to personal jurisdiction in Delaware because, among other things, it has purposely availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here. Aurobindo Pharma USA, Inc. is a corporation organized and existing under the laws of the State of Delaware, is qualified to do business in Delaware, and has appointed a registered agent for service of process in Delaware. It therefore has consented to general jurisdiction in**

Delaware. In addition, on information and belief, Aurobindo Pharma USA, Inc. develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including in the State of Delaware, and therefore transacts business within the State of Delaware related to Merck's claims, and/or has engaged in systematic and continuous business contacts within the State of Delaware.

ANSWER: Paragraph 15 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Aurobindo admits that it is qualified to do business in Delaware, has appointed a registered person for service of process in Delaware, and sells some of its generic products in Delaware. Aurobindo admits that it will not contest personal jurisdiction for the purposes of this action. With respect to any remaining allegations of Paragraph 15, Aurobindo denies the same.

16. **On information and belief, if Aurobindo's ANDA is approved, Aurobindo will manufacture, market, sell, and/or distribute Aurobindo's ANDA Product within the United States, including in Delaware, consistent with Aurobindo's practices for the marketing and distribution of other generic pharmaceutical products. On information and belief, Aurobindo regularly does business in Delaware, and its practices with other generic pharmaceutical products have involved placing those products into the stream of commerce for distribution throughout the United States, including in Delaware. On information and belief, Aurobindo's generic pharmaceutical products are used and/or consumed within and throughout the United States, including in Delaware. On information and belief, Aurobindo's ANDA Product will be prescribed by physicians practicing in Delaware, dispensed by pharmacies located within Delaware, and used by patients in Delaware. Each of these activities would have a substantial effect within Delaware and would constitute**

infringement of Merck's patent in the event that Aurobindo's ANDA Product is approved before the '708 patent or the '921 patent expires.

ANSWER: Paragraph 16 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Aurobindo admits it has done and is doing business in Delaware, and sells drug products in various states of the United States, including Delaware. Due to the variability of market conditions over time, Aurobindo cannot respond one way or the other in regard to its ultimate intentions in regard to engaging in the marketing of Aurobindo ANDA Product in the United States including in the State of Delaware even upon receiving FDA approval to market. Aurobindo admits that it will not contest personal jurisdiction for the purposes of this action. Aurobindo denies the remaining allegations in Paragraph 16.

17. **On information and belief, Aurobindo derives substantial revenue from generic pharmaceutical products that are used and/or consumed within Delaware, and that are manufactured by Aurobindo and/or for which Aurobindo Pharma, Ltd. and/or Aurobindo Pharma USA, Inc. is/are the named applicant(s) on approved ANDAs. On information and belief, various products for which Aurobindo Pharma, Ltd. and/or Aurobindo Pharma USA, Inc. is/are the named applicant(s) on approved ANDAs are available at retail pharmacies in Delaware.**

ANSWER: Paragraph 17 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Aurobindo admits that it derives revenue from its ANDA pharmaceutical products used and/or consumed within Delaware, and that a number of its products are available at retail pharmacies in Delaware. Aurobindo admits that it will not contest personal jurisdiction for the purposes of this action. With respect to any remaining allegations of Paragraph 17, Aurobindo denies the same.

18. **In addition, this Court has personal jurisdiction over Aurobindo because Aurobindo Pharma, Ltd. and Aurobindo Pharma USA, Inc. regularly engage in patent litigation concerning FDA-approved branded drug products in this district, do not contest personal jurisdiction in this district, and have purposefully availed themselves of the rights and benefits of this Court by asserting claims and/or counterclaims in this Court. *See Merck Sharp & Dohme Corp. v. Aurobindo Pharma, Ltd. and Aurobindo Pharma USA, Inc.*, Case No. 20-949-RGA (D. Del. July 15, 2020) (Aurobindo Pharma, Ltd. and Aurobindo Pharma USA, Inc.); *see also Pfizer Inc. v. Aziant Drug Research Sols. Pvt. Ltd.*, C.A. No. 19-743-CFC (D. Del. Apr. 7, 2020) (Aurobindo Pharma, Ltd. and Aurobindo Pharma USA, Inc.); *TaihoPharm. Co. v. Eugia Pharma Specialities Ltd.*, C.A. No. 19-2309-CFC (D. Del. Mar. 23, 2020) (Aurobindo Pharma USA, Inc.); Millennium Pharm. v. Aurobindo Pharma USA, Inc., C.A. No. 19-471-CFC (D. Del. Dec. 26, 2019) (Aurobindo Pharma, Ltd. and Aurobindo Pharma USA, Inc.); Pfizer Inc. v. Aurobindo Pharma, Ltd., C.A. No. 19-748-CFC (D. Del. July 8, 2019) (Aurobindo Pharma, Ltd. and Aurobindo Pharma USA, Inc.).**

ANSWER: Paragraph 18 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Aurobindo admits that it has been involved in litigation in the District of Delaware as indicated in Paragraph 18, and although Aurobindo does not admit that personal jurisdiction is proper, it will not contest personal jurisdiction in the District of Delaware for the limited purposes of this action only. Aurobindo denies the remaining allegations of Paragraph 18.

THE '708 PATENT

19. **Merck incorporates each of the preceding paragraphs 1-18 as if fully set forth herein.**

ANSWER: Aurobindo repeats, reiterates and re-alleges its responses to paragraphs 1 through and including 18 of the Answer to the First Amended Complaint with the same force and effect as if hereinafter set forth at length.

20. **The inventors named on the '708 patent are Stephen Howard Cypes, Alex Minhua Chen, Russell R. Ferlita, Karl Hansen, Ivan Lee, Vicky K. Vydra, and Robert M. Wenslow, Jr.**

ANSWER: Paragraph 20 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Aurobindo admits that, according to the face of U.S. Patent No. '708 as annexed to Plaintiff's First Amended Complaint as Exhibit A, certain persons are named as inventors as set forth above. With respect to any remaining allegations of Paragraph 20, Aurobindo lacks information and knowledge sufficient to form a belief about the truth of such allegations and therefore denies the same.

21. **The '708 patent, entitled "Phosphoric Acid Salt of a Dipeptidyl Peptidase- IV Inhibitor" (attached as Exhibit A), was duly and legally issued on February 5, 2008.**

ANSWER: Paragraph 21 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Aurobindo admits that, according to the face of U.S. Patent No. '708, as set forth at Exhibit A to the First Amended Complaint, the '708 patent was issued on February 5, 2008 with such title. With respect to any remaining allegations of Paragraph 21, Aurobindo lacks information and knowledge sufficient to form a belief about the truth of such allegations and therefore denies the same.

22. **Merck is the owner and assignee of the '708 patent.**

ANSWER: Paragraph 22 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Aurobindo admits that, according to

the face of U.S. Patent No. '708, as set forth at Exhibit A to the First Amended Complaint, Merck & Co., Inc. is the Assignee of the '708 patent, and according to USPTO records, Merck Sharp & Dohme Corp. is the Assignee of the '708 patent. With respect to any remaining allegations of Paragraph 22, Aurobindo lacks information and knowledge sufficient to form a belief about the truth of such allegations and therefore denies the same.

23. **The '708 patent claims, inter alia, a dihydrogenphosphate salt of 4-oxo-4- [3-(trifluoromethyl)-5,6-dihydro[1,2,4]triazolo[4,3-a]pyrazin-7(8H)-yl]-1-(2,4,5-trifluorophenyl)butan-2-amine of structural formula I, or a hydrate thereof, as recited in claim 1 of the '708 patent.**

ANSWER: Paragraph 23 sets forth legal conclusions as to the scope of claims. No response is required. In particular, the interpretation of the claims as to what they cover is a legal matter for which no response is required. With respect to any remaining allegations of Paragraph 23, Aurobindo lacks information and knowledge sufficient to form a belief about the truth of such allegations and therefore denies the same.

24. **JANUMET®, as well as methods of using JANUMET®, are covered by one or more claims of the '708 patent, including claim 1 of the '708 patent, and the '708 patent has been listed in connection with JANUMET® in the FDA's Orange Book.**

ANSWER: Paragraph 24 sets forth legal conclusions based on alleged activities to which no response is required. In particular, the interpretation of the claims as to what they cover is a legal matter for which no response is required. Aurobindo admits that the '708 patent has been listed in connection with JANUVIA® in the FDA's Orange Book. With respect to any remaining

allegations of Paragraph 24, Aurobindo lacks information and knowledge sufficient to form a belief about the truth of such allegations and therefore denies the same.

THE '921 PATENT

25. **Merck incorporates each of the preceding paragraphs 1-24 as if fully set forth herein.**

ANSWER: Aurobindo repeats, reiterates and re-alleges its responses to paragraphs 1 through and including 24 of the Answer to the First Amended Complaint with the same force and effect as if hereinafter set forth at length.

26. **The inventors named on the '921 patent are Ashkan Kamali, Laman Alani, Kyle Fliszar, Soumojeet Ghosh, and Monica Tijerina.**

ANSWER: Paragraph 26 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Aurobindo admits that, according to the face of U.S. Patent No. '921 as annexed to Plaintiff's First Amended Complaint as Exhibit B, certain persons are named as inventors as set forth above. With respect to any remaining allegations of Paragraph 26, Aurobindo lacks information and knowledge sufficient to form a belief about the truth of such allegations and therefore denies the same.

27. **The '921 patent, entitled "Pharmaceutical Compositions of Combinations of Dipeptidyl Peptidase-4 Inhibitors with Metformin" (attached as Exhibit B), was duly and legally issued on April 9, 2013.**

ANSWER: Paragraph 27 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Aurobindo admits that, according to the face of U.S. Patent No. '921, as set forth at Exhibit B to the First Amended Complaint, the '921 patent was issued on April 9, 2013 with such title. With respect to any remaining allegations of

Paragraph 27, Aurobindo lacks information and knowledge sufficient to form a belief about the truth of such allegations and therefore denies the same.

28. **Merck is the owner and assignee of the '921 patent.**

ANSWER: Paragraph 28 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Aurobindo admits that, according to the face of U.S. Patent No. '921, as set forth at First Amended Exhibit B to the First Amended Complaint, Merck & Co., Inc. is the Assignee of the '921 patent, and according to USPTO records, Merck Sharp & Dohme Corp. is the Assignee of the '921 patent. With respect to any remaining allegations of Paragraph 28, Aurobindo lacks information and knowledge sufficient to form a belief about the truth of such allegations and therefore denies the same.

29. **The '921 patent claims, inter alia, a pharmaceutical composition comprising: (a) about 3 to 20% by weight of sitagliptin, or a pharmaceutically acceptable salt thereof; (b) about 25 to 94% by weight of metformin hydrochloride; (c) about 0.1 to 10% by weight of a lubricant; (d) about 0 to 35% by weight of a binding agent; (e) about 0.5 to 1% by weight of a surfactant; and (f) about 5 to 15% by weight of a diluent, as recited in claim 1 of the '921 patent.**

ANSWER: Paragraph 29 sets forth legal conclusions as to the scope of claims. No response is required. In particular, the interpretation of the claims as to what they cover is a legal matter for which no response is required. With respect to any remaining allegations of Paragraph 29,

Aurobindo lacks information and knowledge sufficient to form a belief about the truth of such allegations and therefore denies the same.

30. **JANUMET®, as well as methods of using JANUMET®, are covered by one or more claims of the '921 patent, including claim 1 of the '921 patent, and the '921 patent has been listed in connection with JANUMET® in the FDA's Orange Book.**

ANSWER: Paragraph 30 sets forth legal conclusions based on alleged activities to which no response is required. In particular, the interpretation of the claims as to what they cover is a legal matter for which no response is required. Aurobindo admits that the '921 patent has been listed in connection with JANUMET® in the FDA's Orange Book. With respect to any remaining allegations of Paragraph 30, Aurobindo lacks information and knowledge sufficient to form a belief about the truth of such allegations and therefore denies the same.

COUNT I - INFRINGEMENT OF THE '708 PATENT

31. **Merck incorporates each of the preceding paragraphs 1-30 as if fully set forth herein.**

ANSWER: Aurobindo repeats, reiterates and re-alleges its responses to paragraphs 1 through and including 30 of the First Amended Complaint with the same force and effect as if hereinafter set forth at length.

32. **In Aurobindo's Notice Letter, Aurobindo notified Merck of the submission of Aurobindo's ANDA to the FDA. The purpose of this submission was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Aurobindo's ANDA Product prior to the expiration of the '708 patent.**

ANSWER: Paragraph 32 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Aurobindo admits the contents of its

Notice Letter to Plaintiff and directs Plaintiff to the same. With respect to any remaining allegations of Paragraph 32, Aurobindo denies the same.

33. **In Aurobindo's Notice Letter, Aurobindo also notified Merck that, as part of its ANDA, Aurobindo had filed certifications of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355 (j)(2)(A)(vii)(IV), with respect to the '708 patent. On information and belief, Aurobindo submitted its ANDA to the FDA containing certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '708 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Aurobindo's ANDA Product.**

ANSWER: Paragraph 33 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Aurobindo admits the contents of its Notice Letter to Plaintiff and directs Plaintiff to the same. With respect to any remaining allegations of Paragraph 33, Aurobindo denies the same.

34. **In Aurobindo's Notice Letter, Aurobindo stated that Aurobindo's ANDA Product contains sitagliptin phosphate as an active ingredient.**

ANSWER: Admitted.

35. **Aurobindo's ANDA Product, and the use of Aurobindo's ANDA Product, is covered by one or more claims of the '708 patent, including at least claim 1 of the '708 patent, because claim 1 of the '708 patent covers the sitagliptin phosphate contained in Aurobindo's ANDA Product.**

ANSWER: Paragraph 35 sets forth legal conclusions based on alleged activities to which no response is required. In particular, the interpretation of the claims as to what they cover is a legal matter for which no response is required. With respect to any remaining allegations of

Paragraph 35, Aurobindo lacks information and knowledge sufficient to form a belief about the truth of such allegations and therefore denies the same.

36. **In Aurobindo's Notice Letter, Aurobindo did not contest infringement of claim 1 of the '708 patent.**

ANSWER: Denied.

37. **Aurobindo's submission of Aurobindo's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Aurobindo's ANDA Product before the expiration of the '708 patent was an act of infringement of the '708 patent under 35 U.S.C. § 271(e)(2)(A).**

ANSWER: Denied.

38. **On information and belief, Aurobindo will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Aurobindo's ANDA Product immediately and imminently upon approval of its ANDA.**

ANSWER: Due to the variability of market conditions over time, Aurobindo cannot respond one way or the other in regard to its ultimate intentions in regard to engaging in the marketing of Aurobindo ANDA Product in the United States even upon receiving FDA approval to market, and therefore denies the allegations of Paragraph 38.

39. **The manufacture, use, sale, offer for sale, or importation of Aurobindo's ANDA Product would infringe one or more claims of the '708 patent, including at least claim 1 of the '708 patent.**

ANSWER: Denied.

40. **On information and belief, the manufacture, use, sale, offer for sale, or importation of Aurobindo's ANDA Product in accordance with, and as directed by, its**

proposed product labeling would infringe one or more claims of the '708 patent, including at least claim 1 of the '708 patent.

ANSWER: Denied.

41. **On information and belief, Aurobindo plans and intends to, and will, actively induce infringement of the '708 patent when Aurobindo's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. Aurobindo's activities will be done with knowledge of the '708 patent and specific intent to infringe that patent.**

ANSWER: Denied.

42. **On information and belief, Aurobindo knows that Aurobindo's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '708 patent, that Aurobindo's ANDA Product is not a staple article or commodity of commerce, and that Aurobindo's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. On information and belief, Aurobindo plans and intends to, and will, contribute to infringement of the '708 patent immediately and imminently upon approval of Aurobindo's ANDA.**

ANSWER: Denied.

43. **Notwithstanding Aurobindo's knowledge of the claims of the '708 patent, Aurobindo has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Aurobindo's ANDA Product with its product labeling following FDA approval of Aurobindo's ANDA prior to the expiration of the '708 patent.**

ANSWER: Due to the variability of market conditions over time, Aurobindo cannot respond one way or the other in regard to its ultimate intentions in regard to engaging in the marketing of

Aurobindo ANDA Product in the United States even upon receiving FDA approval to market. With respect to any remaining allegations of Paragraph 43, Aurobindo denies the same.

44. **The foregoing actions by Aurobindo constitute and/or will constitute infringement of the '708 patent; active inducement of infringement of the '708 patent; and contribution to the infringement by others of the '708 patent.**

ANSWER: Denied.

45. **On information and belief, Aurobindo has acted with full knowledge of the '708 patent and without a reasonable basis for believing that it would not be liable for infringement of the '708 patent; active inducement of infringement of the '708 patent; and/or contribution to the infringement by others of the '708 patent.**

ANSWER: Denied.

46. **Merck will be substantially and irreparably damaged by infringement of the '708 patent.**

ANSWER: Denied.

47. **Unless Aurobindo is enjoined from infringing the '708 patent, actively inducing infringement of the '708 patent, and contributing to the infringement by others of the'708 patent, Merck will suffer irreparable injury. Merck has no adequate remedy at law.**

ANSWER: Denied.

COUNT II - DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '708 PATENT

48. **Merck incorporates each of the preceding paragraphs 1-47 as if fully set forth herein.**

ANSWER: Aurobindo repeats, reiterates and re-alleges its responses to paragraphs 1 through and including 47 of the First Amended Complaint with the same force and effect as if hereinafter set forth at length.

49. **The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Merck on the one hand and Aurobindo on the other regarding Aurobindo's infringement, active inducement of infringement, and contribution to the infringement by others of the '708 patent.**

ANSWER: Paragraph 49 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Aurobindo admits for the purpose of this action personal and subject matter jurisdiction. With respect to any remaining allegations of Paragraph 49, Aurobindo denies the same.

50. **The Court should declare that the commercial manufacture, use, sale, offer for sale or importation of Aurobindo's ANDA Product with its proposed labeling, or any other Aurobindo drug product that is covered by or whose use is covered by the '708 patent, will infringe, induce the infringement of, and contribute to the infringement by others of the '708 patent, and that the claims of the '708 patent are valid.**

ANSWER: Denied.

COUNT III - INFRINGEMENT OF THE '921 PATENT

51. **Merck incorporates each of the preceding paragraphs 1-50 as if fully set forth herein.**

ANSWER: Aurobindo repeats, reiterates and re-alleges its responses to paragraphs 1 through and including 50 of the First Amended Complaint with the same force and effect as if hereinafter set forth at length.

52. **In Aurobindo's Notice Letter, Aurobindo notified Merck of the submission of Aurobindo's ANDA to the FDA. The purpose of this submission was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Aurobindo's ANDA Product prior to the expiration of the '921 patent.**

ANSWER: Paragraph 52 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Aurobindo admits the contents of its Notice Letter to Plaintiff and directs Plaintiff to the same. With respect to any remaining allegations of Paragraph 52, Aurobindo denies the same.

53. **In Aurobindo's Notice Letter, Aurobindo also notified Merck that, as part of its ANDA, Aurobindo had filed certifications of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355 (j)(2)(A)(vii)(IV), with respect to the '921 patent. On information and belief, Aurobindo submitted its ANDA to the FDA containing certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '921 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Aurobindo's ANDA Product.**

ANSWER: Paragraph 53 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Aurobindo admits the contents of its Notice Letter to Plaintiff and directs Plaintiff to the same. With respect to any remaining allegations of Paragraph 53, Aurobindo denies the same.

54. **Aurobindo's ANDA Product, and the use of Aurobindo's ANDA Product, is covered by one or more claims of the '921 patent, including at least claim 1 of the '921 patent, because the composition of Aurobindo's ANDA Product includes the same or equivalent ingredients as recited in claim 1 of the '921 patent in the same or equivalent amounts.**

ANSWER: Paragraph 54 sets forth legal conclusions based on alleged activities to which no response is required. In particular, the interpretation of the claims as to what they cover is a legal matter for which no response is required. With respect to any remaining allegations of Paragraph 54, Aurobindo lacks information and knowledge sufficient to form a belief about the truth of such allegations and therefore denies the same.

55. **Aurobindo's submission of Aurobindo's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Aurobindo's ANDA Product before the expiration of the '921 patent was an act of infringement of the '921 patent under 35 U.S.C. § 271(e)(2)(A).**

ANSWER: Denied.

56. **On information and belief, Aurobindo will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Aurobindo's ANDA Product immediately and imminently upon approval of its ANDA.**

ANSWER: Due to the variability of market conditions over time, Aurobindo cannot respond one way or the other in regard to its ultimate intentions in regard to engaging in the marketing of Aurobindo ANDA Product in the United States even upon receiving FDA approval to market, and therefore denies the allegations of Paragraph 56.

57. **The manufacture, use, sale, offer for sale, or importation of Aurobindo's ANDA Product would infringe one or more claims of the '921 patent, including at least claim 1 of the '921 patent.**

ANSWER: Denied.

58. **On information and belief, the manufacture, use, sale, offer for sale, or importation of Aurobindo's ANDA Product in accordance with, and as directed by, its proposed product labeling would infringe one or more claims of the '921 patent, including at least claim 1 of the '921 patent.**

ANSWER: Denied.

59. **On information and belief, Aurobindo plans and intends to, and will, actively induce infringement of the '921 patent when Aurobindo's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. Aurobindo's activities will be done with knowledge of the '921 patent and specific intent to infringe that patent.**

ANSWER: Denied.

60. **On information and belief, Aurobindo knows that Aurobindo's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '921 patent, that Aurobindo's ANDA Product is not a staple article or commodity of commerce, and that Aurobindo's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use.**

ANSWER: Denied.

61. **On information and belief, Aurobindo plans and intends to, and will, contribute to infringement of the '921 patent immediately and imminently upon approval of Aurobindo's ANDA.**

ANSWER: Denied.

62. **Notwithstanding Aurobindo's knowledge of the claims of the '921 patent, Aurobindo has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Aurobindo's ANDA Product with its product labeling following FDA approval of Aurobindo's ANDA prior to the expiration of the '921 patent.**

ANSWER: Due to the variability of market conditions over time, Aurobindo cannot respond one way or the other in regard to its ultimate intentions in regard to engaging in the marketing of Aurobindo ANDA Product in the United States even upon receiving FDA approval to market. With respect to any remaining allegations of Paragraph 62, Aurobindo denies the same.

63. **The foregoing actions by Aurobindo constitute and/or will constitute infringement of the '921 patent; active inducement of infringement of the '921 patent; and contribution to the infringement by others of the '921 patent.**

ANSWER: Denied.

64. **On information and belief, Aurobindo has acted with full knowledge of the '921 patent and without a reasonable basis for believing that it would not be liable for infringement of the '921 patent; active inducement of infringement of the '921 patent; and/or contribution to the infringement by others of the '921 patent.**

ANSWER: Denied.

65. **Merck will be substantially and irreparably damaged by infringement of the '921 patent.**

ANSWER: Denied.

66. **Unless Aurobindo is enjoined from infringing the '921 patent, actively inducing infringement of the '921 patent, and contributing to the infringement by others of the '921 patent, Merck will suffer irreparable injury. Merck has no adequate remedy at law.**

ANSWER: Denied.

COUNT IV - DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '921 PATENT

67. **Merck incorporates each of the preceding paragraphs 1-66 as if fully set forth herein.**

ANSWER: Aurobindo repeats, reiterates and re-alleges its responses to paragraphs 1 through and including 66 of the First Amended Complaint with the same force and effect as if hereinafter set forth at length.

68. **The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Merck on the one hand and Aurobindo on the other regarding Aurobindo's infringement, active inducement of infringement, and contribution to the infringement by others of the '921 patent.**

ANSWER: Paragraph 68 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Aurobindo admits for the purpose of this action personal and subject matter jurisdiction. With respect to any remaining allegations of Paragraph 68, Aurobindo denies the same.

69. **The Court should declare that the commercial manufacture, use, sale, offer for sale or importation of Aurobindo's ANDA Product with its proposed labeling, or any other Aurobindo drug product that is covered by or whose use is covered by the '921 patent, will**

infringe, induce the infringement of, and contribute to the infringement by others of the '921 patent, and that the claims of the '921 patent are valid.

ANSWER: Denied.

PLAINTIFF'S PRAYER FOR RELIEF

WHEREFORE, Merck requests the following relief:

(a) **A judgment that the '708 patent has been infringed under 35 U.S.C. § 271(e)(2) by Aurobindo's submission to the FDA of Aurobindo's ANDA;**

(b) **A judgment ordering that the effective date of any FDA approval of the commercial manufacture, use, or sale of Aurobindo's ANDA Product, or any other drug product that infringes or the use of which infringes the '708 patent, be not earlier than the latest of the expiration date of the '708 patent, inclusive of any extension(s) and additional period(s) of exclusivity;**

(c) **A preliminary and permanent injunction enjoining Aurobindo, and all persons acting in concert with Aurobindo, from the commercial manufacture, use, sale, offer for sale, or importation into the United States of Aurobindo's ANDA Product, or any other drug product covered by or whose use is covered by the '708 patent, prior to the expiration of the '708 patent, inclusive of any extension(s) and additional period(s) of exclusivity;**

(d) **A judgment declaring that the commercial manufacture, use, sale, offer for sale or importation of Aurobindo's ANDA Product, or any other drug product that is covered by or whose use is covered by the '708 patent, prior to the expiration of the '708 patent, will infringe, induce the infringement of, and contribute to the infringement by others of, the '708 patent;**

(e) **A judgment that the '921 patent has been infringed under 35 U.S.C. § 271(e)(2) by Aurobindo's submission to the FDA of Aurobindo's ANDA;**

(f) **A judgment ordering that the effective date of any FDA approval of the commercial manufacture, use, or sale of Aurobindo's ANDA Product, or any other drug product that infringes or the use of which infringes the '921 patent, be not earlier than the latest of the expiration date of the '921 patent, inclusive of any extension(s) and additional period(s) of exclusivity;**

(g) **A preliminary and permanent injunction enjoining Aurobindo, and all persons acting in concert with Aurobindo, from the commercial manufacture, use, sale, offer for sale, or importation into the United States of Aurobindo's ANDA Product, or any other drug product covered by or whose use is covered by the '921 patent, prior to the expiration of the '921 patent, inclusive of any extension(s) and additional period(s) of exclusivity;**

(h) **A judgment declaring that the commercial manufacture, use, sale, offer for sale or importation of Aurobindo's ANDA Product, or any other drug product that is covered by or whose use is covered by the '921 patent, prior to the expiration of the '921 patent, will infringe, induce the infringement of, and contribute to the infringement by others of, the '921 patent;**

(i) **A declaration that this is an exceptional case and an award of attorney's fees pursuant to 35 U.S.C. § 285;**

(j) **Costs and expenses in this action; and**

(k) **Such further and other relief as this Court may deem just and proper.**

ANSWER TO PRAYER FOR RELIEF: The "WHEREFORE" paragraphs following Paragraph 69 states Plaintiff's prayer for relief for which no response is required. To the extent a

response is required, Defendants deny the allegations contained in the "WHEREFORE" paragraphs following Paragraph 69 of the First Amended Complaint and deny that Plaintiff is entitled to any of the relief required, or to any relief whatsoever. Aurobindo specifically denies that Plaintiff is entitled to the general or specific relief requested against Aurobindo, or to any relief whatsoever, and pray for judgment in favor of Aurobindo dismissing this action with prejudice, and awarding Aurobindo its reasonable attorneys' fees.

ADDITIONAL DEFENSES

Aurobindo asserts the following defenses without prejudice to the denials in this Answer, without admitting any allegations of the First Amended Complaint not otherwise admitted.

FIRST ADDITIONAL DEFENSE
(FAILURE TO STATE A CLAIM)

Plaintiff's First Amended Complaint, in whole or in part, fails to state claims upon which relief may be granted.

SECOND ADDITIONAL DEFENSE
(INVALIDITY AND UNENFORCEABILITY)

United States Patent No. 7,326,708 ("the '708 patent") and United States Patent No. 8,414,921 ("the '921 patent") (together, the "Patents-In-Suit") and each of the claims thereof, are invalid and/or unenforceable for failure to comply with one or more conditions for patentability and/or enforceability set forth in one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidity and/or unenforceability, as more particularly set forth in the July 10, 2020 Notice Letter ("Aurobindo's Notice Letter") sent in respect Aurobindo's Paragraph IV Certifications ("Aurobindo's Paragraph IV Certification").

THIRD ADDITIONAL DEFENSE
(NO DIRECT INFRINGEMENT)

As set forth in the Detailed Statement of Aurobindo's Notice Letter, Aurobindo does not infringe literally any valid and enforceable claim of the Patents-In-Suit and thus cannot be said to literally infringe the same. As no equivalent can be found in Aurobindo's proposed product for the missing elements of any of the claims of the Patents-In-Suit, there can be no infringement under the doctrine of equivalents.

FOURTH ADDITIONAL DEFENSE
(NO INDIRECT INFRINGEMENT)

Aurobindo has not, does not, and will not induce the infringement of, or contribute to the infringement of, any valid and enforceable claim of the Patents-In-Suit, and the manufacturing, marketing, sale, offer for sale, importation, and/or distribution of the Aurobindo ANDA product does not induce the infringement of, or contribute to the infringement of, any valid and enforceable claim of the Patents-In-Suit.

FIFTH ADDITIONAL DEFENSE
(NO COSTS)

Plaintiff is barred by 35 U.S.C. § 288 from recovering any costs associated with this suit.

SIXTH ADDITIONAL DEFENSE
(FAILURE TO STATE CLAIM OF WILFULNESS)

Plaintiff fails to state a proper claim for willful infringement or exceptional case under 35 §§ 271(e)(4) and 285, or otherwise.

SEVENTH ADDITIONAL DEFENSE
(RESERVATION OF RIGHTS)

Aurobindo reserves the right to assert additional defenses or counterclaims that discovery may reveal.

COUNTERCLAIMS OF AUROBINDO

Pursuant to Rule 13 of the Federal Rules of Civil Procedure, Aurobindo Pharma USA, Inc. and Aurobindo Pharma Ltd. ("Aurobindo" or "Counterclaim-Plaintiffs"), through their undersigned attorneys, for their Counterclaims against Merck Sharp & Dohme Corp. ("Merck" or "Counterclaim-Defendant"), hereby state the following:

1. Counterclaim-Plaintiffs repeat and incorporate by reference each of the foregoing paragraphsof Aurobindo's (Defendants') Answer and Additional Defenses to the First Amended Complaint.

2. This is an action for a declaratory judgment of non-infringement and invalidity of the claims of United States Patent No. 7,326,708 ("the '708 patent") and United States Patent No. 8,414,921 ("the '921 patent") (together, the "Patents-In-Suit"). Upon information and belief, a true and correct copy of the '708 patent is attached to the First Amended Complaint as Exhibit A. Upon information and belief, a true and correct copy of the '921 patent is attached to the First Amended Complaint as Exhibit B.

THE PARTIES

3. Counterclaim-Plaintiff Aurobindo Pharma USA, Inc. is a corporation organized and existing under the laws of Delaware, having a place of business at 279 Princeton-Hightstown Rd., East Windsor, NJ 08520-1401 USA.

4. Counterclaim-Plaintiff Aurobindo Pharma Ltd. is an Indian corporation having a place of business at Plot No. 2, Maitri Vihar, Ameerpet, Hyderabad – 500 038, Andra Pradesh, India.

5. On information and belief, based on the complaint filed by Plaintiff/Counterclaim-Defendant in this case, Counterclaim-Defendant Merck is a corporation organized and existing

under the laws of New Jersey, having its corporate offices and principal place of business at One Merck Drive, Whitehouse Station, New Jersey 08889.

JURISDICTION

6. This Court has subject matter jurisdiction over these Counterclaims for declaratory judgment pursuant to 28 U.S.C. §§ 1331, 1337(a), 1338(a), 2201(a) and (b), and 2202, based on an actual controversy between Counterclaim-Plaintiffs, on the one hand, and the Counterclaim-Defendant on the other hand, arising under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*

7. This Court has personal jurisdiction over Counterclaim-Defendant based, *inter alia,* on the filing by Counterclaim-Defendant of this lawsuit in this jurisdiction and because Counterclaim-Defendant is doing business in this jurisdiction.

8. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c), and 1400(b).

ORANGE BOOK LISTING OF THE PATENTS

9. The Hatch-Waxman Amendments to the Food, Drug and Cosmetic Act require NDA holders to disclose to the FDA the patent numbers and expiration dates of those patents that the holder believes claim the "drug" for which their NDA is submitted, or patents covering a "method of using such drug." 21 U.S.C. §§ 355(b)(1) and (c)(2).

10. On information and belief, on February 5, 2008, the U.S. Patent and Trademark Office ("PTO") issued the '708 Patent. On information and belief, a true and correct copy of the '708 Patent is attached to the First Amended Complaint as Exhibit A.

11. On information and belief, on April 9, 2013, the U.S. Patent and Trademark Office ("PTO") issued the '921 Patent. On information and belief, a true and correct copy of the '921 Patent is attached to the First Amended Complaint as Exhibit B.

12. On information and belief, pursuant to 21 U.S.C. §§ 355(b)(l), Counterclaim-Defendant caused the FDA to list the Patents-In-Suit in the Orange Book in connection with NDA No. 21995 in respect of the brand name product JANUMET® (generic name sitagliptin phosphate metformin hydrochloride) ("Janumet NDA").

13. By maintaining the listings of the Patents-In-Suit in the Orange Book, Counterclaim-Defendant represents to the world that the Patents-In-Suit could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale (21 U.S.C. § 355(b)(l)) of the respective brand name product before the expiration of the Patents-in-Suit.

AUROBINDO'S ABBREVIATED NEW DRUG APPLICATION

14. Aurobindo filed ANDA No. 214859 ("Aurobindo's ANDA") with the FDA seeking approval to market a generic sitagliptin phosphate metformin hydrochloride, intended to be a generic version of JANUMET®. Aurobindo's ANDA included a Paragraph IV Certification to the Patents-In-Suit, certifying that to the best of its knowledge that all of the claims of the Patents-In-Suit are invalid, unenforceable, and/or will not be infringed by the manufacture, use, sale, offer to sell, and/or importation of the product described in Aurobindo's ANDA.

THE PRESENCE OF A CASE OR CONTROVERSY

15. By maintaining the Orange Book listing of the Patents-In-Suit in connection with the JANUMET®, Counterclaim-Defendant represents that the Patents-In-Suit could reasonably be asserted against anyone making, using or selling generic sitagliptin phosphate metformin

hydrochloride tablets, intended to be generic version of JANUMET®, without a license from the Counterclaim-Defendant prior to the expiration of the Patents-In-Suit.

16. Counterclaim-Defendant has filed an infringement action under Title 35, United States Code, Sections 100 et seq., asserting the Patents-In-Suit against Counterclaim-Plaintiffs and seeking a declaration of infringement regarding the Patents-In-Suit. There has been, and is now, an actual and justiciable controversy between Counterclaim-Plaintiffs on the one hand, and Counterclaim-Defendant, on the other hand, as to whether the products disclosed in Aurobindo's ANDA infringe the Patents-In-Suit, and whether any valid, enforceable claim in the Patents-In-Suit exists.

17. Aurobindo seeks to market generic sitagliptin phosphate metformin hydrochloride tablets that are the subject of Aurobindo's ANDA in the United States prior to the expiration of the Patent-In-Suit.

18. If Counterclaim-Plaintiffs succeed in proving that their generic sitagliptin phosphate metformin hydrochloride tablets that are the subject of Aurobindo's ANDA do not infringe the Patents-In-Suit or all asserted claims are invalid or unenforceable, and thus non-infringing, such a judgment will remove any uncertainty that may exist by virtue of Counterclaim-Defendant's maintenance of the Patents-In-Suit in the Orange Book in connection with the Janumet® NDA.

19. In light of all the circumstances, an actual substantial and continuing justiciable controversy having sufficient immediacy and reality to warrant the issuance of a declaration of rights by the Court exists between Counterclaim-Defendant and Counterclaim-Plaintiffs as to whether the claims of the Patents-In-Suit are invalid and/or not infringed by Counterclaim-Plaintiffs.

COUNT I

(DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE PATENTS-IN-SUIT)

20. Counterclaim-Plaintiffs repeat and incorporates by reference Paragraphs 1-19 of their Counterclaims, above, as if fully set forth herein.

21. This counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.,* and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. A case of actual, substantial, and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between Counterclaim-Plaintiffs and Counterclaim-Defendant concerning the Patents-In-Suit and the claims of the Patents-In-Suit.

22. Counterclaim-Defendant alleges that the commercial manufacture, use, offer for sale, sale, and/or importation of Counterclaim-Plaintiffs' generic sitagliptin phosphate metformin hydrochloride product that is the subject of Aurobindo's ANDA infringes one or more claims of the Patents-In-Suit.

23. Counterclaim-Plaintiffs assert that no valid claim of the Patents-In-Suit is infringed by the manufacture, use, offer for sale, sale, and/or importation of generic sitagliptin phosphate metformin hydrochloride tablets that are the subject of Aurobindo's ANDA.

24. Counterclaim-Plaintiffs are entitled to a declaration that the manufacture, use, offer for sale, sale, and/or importation of Counterclaim-Plaintiff's' generic sitagliptin phosphate metformin hydrochloride tablets that are the subject of Aurobindo's ANDA, do not infringe any valid claim of the Patents-In-Suit.

COUNT II

(DECLARATORY JUDGMENT OF INVALIDITY OF THE PATENT-IN-SUIT)

25. Counterclaim-Plaintiffs repeat and incorporates by reference Paragraphs 1-24 of Counterclaim-Plaintiffs' Counterclaims, above, as if fully set forth herein.

26. This counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.,* and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. A case of actual, substantial, and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between Counterclaim-Plaintiffs and Counterclaim-Defendant concerning the claims of the Patents-In-Suit.

27. Counterclaim-Defendant alleges that the commercial manufacture, use, offer for sale, sale, and/or importation of Counterclaim-Plaintiffs' generic sitagliptin phosphate metformin hydrochloride tablets that are the subject of Aurobindo's ANDA, infringes one or more claims of the Patents-In-Suit.

28. Counterclaim-Plaintiffs assert that the manufacture, use, offer-for-sale, sale, and/or importation of Counterclaim-Plaintiffs' generic sitagliptin phosphate metformin hydrochloride tablets that are the subject of Aurobindo's ANDA do not infringe any valid claim of the Patents-In-Suit, and that the claims of the Patent-In-Suit are invalid under one or more provisions of 35 U.S.C. §§ 101, 103, 103, or 112, or other judicially-created bases for invalidation for all the reasons set forth in Aurobindo's July 10, 2020 Notice Letter (which Counterclaim-Plaintiffs can resupply if needed).

29. Counterclaim-Plaintiffs are entitled to a declaration that the claims of the Patents-In-Suit are invalid under one or more provisions of 35 U.S.C. §§ 101, 103, 103, or 112, or other judicially-created bases for invalidation.

PRAYER FOR RELIEF

WHEREFORE, Counterclaim-Plaintiffs respectfully request that the Court enter judgment in their favor and against Counterclaim-Defendant as follows:

a. Denying Counterclaim-Defendant's claims and dismissing Plaintiff's First Amended Complaint with prejudice.

b. Declaring that the claims of the Patents-In-Suit are invalid;

c. Declaring that the claims of the Patents-In-Suit are not, and will not be, infringed by Counterclaim-Plaintiffs' manufacture, use, sale, offer for sale, or importation of the generic sitagliptin phosphate metformin hydrochloride tablets that is the subject of Aurobindo's ANDA;

d. Preliminarily and permanently enjoining Counterclaim-Defendant, its officers, agents, servants, employees, attorneys, and any person who acts in concert or participation with Counterclaim-Defendant, from utilizing the Patents-In-Suit to block, hamper, hinder or obstruct FDA approval of Counterclaim-Plaintiffs' proposed product;

e. Permanently enjoining Counterclaim-Defendant, its officers, agents, servants, employees, attorneys, and any person who acts in concert or participation with Counterclaim-Defendant, from asserting or otherwise seeking to enforce the Patents-In-Suit against Counterclaim-Plaintiffs or anyone in privity with Counterclaim-Plaintiffs;

f. Declaring this case exceptional and awarding Counterclaim-Plaintiffs their attorneys' fees pursuant to 35 U.S.C. § 285, the inherent power of this Court, or otherwise;

g. Awarding costs to Counterclaim-Plaintiffs; and

h. Awarding to Counterclaim-Plaintiffs any other such and further relief as is just and proper.

Dated: March 3, 2021

SMITH, KATZENSTEIN & JENKINS LLP

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